CIRM Funded Clinical Trials

A Human Acellular Vessel in Patients Needing Renal Replacement Therapy: A Comparison with ePTFE Grafts as Conduits for Hemodialysis (HUMANITY)

Disease Area:	Kidney Failure
Investigator:	Jeffrey Lawson
Institution:	Humacyte, Inc.
CIRM Grant:	CLIN2-08938
Award Value:	$9,999,528
Trial Sponsor:	Humacyte, Inc.
Trial Stage:	Phase 3
Trial Status:	Active, not recruiting
Targeted Enrollment:	355
ClinicalTrials.gov ID:	NCT02644941

Jeffrey Lawson

Details:
Humacyte is using donor cells to create a bioengineered vein needed by people with end-stage kidney failure undergoing hemodialysis, the most common form of dialysis. In dialysis a person is connected to a machine that removes waste from their blood. The bioengineered vein is called a Human Acellular Vessel (HAV) and is made of extracellular matrix from human smooth muscle cells, similar in composition and structure to native tissue. The HAV is implanted in a patient's arm and used to carry their blood to and from their body during dialysis. Over time the patient's own stem cells start to populate this vein, in effect making it part of the patient's own body. Humacyte's HAV is being compared head-to-head with the current standard of care as well as a synthetic product that is used by some patients who are not candidates for the standard treatment.

Design:
Randomized, open-label, 2 arm study comparing HAV to ePTFE grafts in patients with end-stage renal disease.

Goal:
Primary: Safety and tolerability, rate of patency of the graft and rate of interventions needed to restore patency.

Updates:
Enrolling ahead of schedule. 300 patients worldwide, including 47 in CA (as of May 2017). Received RMAT designation March 2017. Plan to file BLA in April 2019.

News Releases:
California Institute for Regenerative Medicine Awards $9.9 Million Grant for the Development of HUMACYL®
New FDA Pathway to Accelerate Development of Cell Therapies

Humacyte Completes Patient Enrollment for Phase III Clinical Trial of Human Acellular Vessel

Contact Trial Sponsor

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